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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,443	07/03/2003	Eric A. Goldfarb	020489-000120US	6557

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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/613,443

Applicant(s)

GOLDFARB ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 67, 68 and 70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 and 67 is/are allowed.
- 6) ☒ Claim(s) 68 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/2/06, 2/13/04, 12/29/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments/Remarks

Examiner acknowledges amendments to objected claims 20, 67, 68 and 70 to include limitations intervening and base claims, the indicated allowability of claims 68 and 70 is withdrawn in view of the newly discovered reference(s) to Oz. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 68 is rejected under 35 U.S.C. 102(e) as being anticipated by Oz et al. (US 6269819).

Regarding Claim 68, Oz teaches an apparatus for repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side, and an inferior surface on an opposing side, the apparatus comprising: a pair of articulating arms coupled together (fig. 20) and movable from an open position in which portions of the articulating arms are spaced apart (fig. 19) to a closed position in which the portions of the articulating arms are closer together (fig. 18), said arms having engaging surfaces (136) for engaging the surfaces of the leaflets and being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration in which portions of the superior surfaces are facing each other (fig. 20); wherein the articulating arms are implantable in the patients body to maintain the leaflets in a coapted configuration (fig. 20); and a control mechanism (132) operatively coupled to the articulating arms, wherein the control mechanism is adapted to open and close the pair of articulating arms, each articulating arm being independently movable (for example, column 6, proximate lines 16-23), and wherein the articulating arms can be closed to engage the leaflets and thereafter opened to release the leaflets (it is noted that since the arms are not locked into their closed positions until portion 138 is deployed, the arms may be opened and closed as many times as needed before deploying portion 138).

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch et al. (US 6117159) in view of Laufer et al. (US 5810847), and further in view of Oz et al. (US 6269819).

Huebsch teaches an apparatus capable of repairing a valve in a patient's body, the valve having a plurality of movable leaflets, the leaflets having a superior surface on a first side and an inferior surface on an opposing side, the apparatus comprising:

- a pair of articulating arms (24) coupled together and movable from an open position in which portions of the articulating arms are spaced apart (proximal-most and distal-most portions of arm 24, fig. 2) to a closed position in which the portions of the arms are closer together (fig. 4),

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- said arms being configured to engage the inferior surfaces of the leaflets and hold the leaflets in a coapted configuration (fig. 5a) wherein the arms are implantable in the patient's body to maintain the leaflets in the coapted configuration (fig. 5a);
- a control mechanism operatively coupled to the articulating arms and adapted to open and close the pair of articulating arms, wherein the arms can be closed to engage the leaflets and thereafter be opened to allow release of the leaflets (claim 7)
- the apparatus further comprising a central member (18), the arms being movably coupled to the central member
- A pair of superior elements (22) movably coupled to the central member (18), the superior elements being configured to engage the superior surfaces whereby the leaflets may be pinched between the articulating arms and the superior elements (fig. 5a)
- wherein the articulating arms (24) have engaging surfaces capable of engaging the surfaces of the leaflets

Huebsch fails to teach wherein the device is capable of holding the leaflets such that portions of the superior surfaces are facing each other. It would have been an obvious matter of design choice to provide the device of Huebsch such that it is capable of holding the leaflets such that portions of the superior surfaces are facing each other as taught by Laufer, since applicant has not disclosed that such a feature provides any advantage over holding the portions such that they are simply in line with each other,

and it appears that the device of Huebsch performs the task of holding two portions of the heart in a coapted configuration equally well as that of the disclosed application, and it is known to hold valve leaflets in a coapted configuration wherein portions of the superior surfaces of the leaflets are facing each other.

The combination of Huebsch and Laufer fails to teach wherein the control mechanism is adapted to open and close the articulating arms independently. Oz teaches a device capable of repairing a valve in a patients body comprising articulating arms, wherein the arms may be moved independently in order to provide precise control over the individual elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Huebsch and Laufer as taught by Oz in order to provide precise control over the individual elements.

Allowable Subject Matter

Claims 20 and 67 are allowed. The following is a statement of reasons for the indication of allowable subject matter: The prior art, alone or in combination fails to teach all limitations of claims 20 and 67. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
3/16/07


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

3/17/07